

**REMARKS**

Applicant thanks the Examiner for acknowledging Applicant's claim to foreign priority under 35 U.S.C. § 119(a)-(d), and for confirming that the certified copy of the priority document has been received at the Patent Office.

**Information Disclosure Statement:**

Applicant thanks the Examiner for initialing and returning Forms PTO-1449 filed on June 19, 2000 and September 11, 2002, thus indicating that all of the references listed thereon have been considered.

**Election/Restriction:**

Applicant sincerely thanks the Examiner for reconsidering and withdrawing the restriction requirement set forth in the September 19, 2002 Action.

In light of this withdrawal, Applicant hereby submits that Applicant will allow U.S. Application No.: 10/300,032, which was filed on November 20, 2002 in response to the above restriction requirement, to go abandoned. Applicant notes that the claims of the '032 application will now be pursued in the above referenced application, and have been added in their entirety.

Further, Applicant notes that the abandonment of the '032 application is in no way an admission of any kind, as the subject matter and claims of the '032 application are fully incorporated herein.

**Claim Objections:**

Claims 4-8, 10 and 13-15 are objected to under 37 C.F.R. § 1.75(c) as being in improper form. Applicant notes that Applicant filed a Preliminary Amendment on November 20, 2002, which eliminated the multiple dependency of the above claims.

Applicant hereby requests the Examiner reconsider the above objection, in view of the November 20, 2002 Preliminary Amendment, and withdraw the above objection to the claims.

**Claim Rejections:**

Claims 1-16 are all of the claims that have been examined in the present application, and currently all of these claims stand rejected.

***35 U.S.C. § 112, 2<sup>nd</sup> Paragraph Rejection - Claims 15 and 16:***

Claims 15 and 16 stand rejected under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph as being indefinite. Specifically, the Examiner has indicated that these claims do not set forth any steps involved in the method or process. Applicant has amended claims 15 and 16 as shown in the attached Appendix, and hereby submits that these claims address all of the Examiner's concerns. Therefore, Applicant hereby requests the Examiner reconsider and withdraw the above 35 U.S.C. § 112, 2<sup>nd</sup> paragraph rejection of claims 15 and 16.

***35 U.S.C. § 101 rejection - Claims 15 and 16:***

Claims 15 and 16 stand rejected under 35 U.S.C. § 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process.

As discussed above, Applicant has amended claims 15 and 16 as shown in the attached Appendix, to address the Examiner's concerns. In view of the amendments to claims 15 and 16, Applicant hereby requests the Examiner reconsider and withdraw the above 35 U.S.C. § 101 rejection of these claims.

***35 U.S.C. § 103(a) Rejection - Claims 1-16:***

Claims 1-16 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,370,476 to Usher et al. In view of the following comments, Applicant respectfully disagrees.

Applicant submits that Usher discloses dextran derivatives having internal pairs of carboxylic groups and optional one terminal carboxylic or hydroxy group. In contrast, the dextran derivatives according to the present invention have no internal carboxylic groups and have either a terminal carboxylic group or a terminal hydroxy group.

Applicant also notes that the processes for preparing the dextran derivatives in Usher, as compared to the present invention, are fundamentally different. Usher discloses a process comprising the following steps: (1) an optional hydrogenation step; (2) a first oxidation in order to introduce internal aldehyde groups in the dextran; and (3) a second oxidation step in order to convert internal and terminal aldehyde groups into carboxylic groups. In contrast, in the present invention, a partial hydrogenation step is followed by only one oxidation step.

Applicant submits that a skilled artisan would appreciate that the dextran compound disclosed by Usher will have a significantly stronger acidic character than the dextran compound according to the present invention, because Usher's dextran molecules comprise, on average, 2 or more carboxylic acid groups, whereas the dextran molecules according to the present invention comprise, on average, less than one carboxylic acid group. Further, it is noted that it is a particular feature of the Usher molecules that they possess carboxylic groups in pairs, which

finds no counterpart in the present application because none of the molecules have more than one carboxylic group. *See* claim 1 of Usher.

Further, Applicant notes that a skilled artisan would appreciate that the interaction between Usher's dextran derivatives and iron will be influenced by the pluralities of carboxylic groups and, therefore, the iron dextran prepared from these different dextrans will be significantly different.

Additionally, Applicant further notes that in no way would a skilled artisan arrive at the present invention, by simply using the Usher disclosure, because the method according to the present invention excludes the presence of "a plurality of pairs of carboxylic acid groups," which is contrary to the mandatory demand for such pairs in Usher.

In view of the foregoing discussion, Applicant submits that the Examiner has failed to establish a *prima facie* case of obviousness with respect to claims 1 and 9, and hereby requests the Examiner reconsider and withdraw the above 35 U.S.C. § 103(a) rejection of these claims. Further, as claims 2-8 and 10-16 depend on these claims, Applicant also submits that these claims are allowable, at least by reason of their dependence.

***35 U.S.C. § 103(a) rejection - Claims 8 and 14:***

Claims 8 and 14 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Usher in view of U.S. Patent No. 3,549,614 to Mioduszewski et al.

As an initial matter, Applicant notes that because claims 8 and 14 depend on claim 1, and because Mioduszewski fails to cure the deficient teachings of Usher, with regard to claim 1, Applicant submits that claims 8 and 14 are also allowable, at least by reason of their dependence.

However, Applicant additionally notes that one of ordinary skill in the art would not be motivated to combined the teachings of Usher with Mioduszewski to obtain the present invention. Specifically, Applicant notes that because Usher requires the dextran compound to contain pairs of carboxylic acid groups, which is excluded by the method for preparation of the dextran compounds of the present invention, one of ordinary skill in the art would not be motivated to combine the teachings of the above references.

***35 U.S.C. § 101 Rejection - Claims 9, 11 and 16:***

Claims 9, 11 and 16 stand provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as claims 17, 24 and 26 of pending U.S. Application No.: 10/300,032.

As Applicant has previously indicated, the '032 application was filed by Applicant in response to the September 19, 2002 restriction requirement. However, in view of the Examiner's withdrawal of the restriction requirement, Applicant will allow the '032 application to go abandoned, by failing to respond to the March 12, 2003 Office Action in that application.

However, Applicant notes that such an abandonment is contingent on the Examiner's withdrawal of the September 19, 2003 restriction requirement.

In view of the foregoing, Applicant submits that the above rejection is now moot.

***Obviousness-Type Double Patenting Rejection - Claims 1-16:***

Claims 1-16 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of U.S. Patent No. 6,291,440. Applicant respectfully disagrees.

Applicant notes that the claims of the present application are drawn to iron dextran prepared from a dextran compound prepared by a hydrogenation followed by oxidation, while the claims from the '440 patent recite an iron-dextran compound prepared from a dextran compound having an average molecular weight in the range of 700 to 1400 Daltons. Therefore, Applicant submits that the claimed subject matter of the present application is patentably distinct from the subject matter of the '440 patent.

In view of the foregoing, Applicant hereby requests the Examiner reconsider and withdraw the above double patenting rejection of claims 1-16.

***Obviousness-Type Double Patenting Rejection - Claims 1-8, 10 and 12-15:***

Claims 1-8, 10 and 12-15 also stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 18-23 of U.S. Application No.: 10/300,032. In view of the above discussions regarding the '032 application, Applicant hereby submits that the above rejection is now moot and should be withdrawn.

**Conclusion:**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

AMENDMENT UNDER 37 C.F.R. § 1.111  
U.S. Application No.: 09/509,681

Our Ref.: Q58461  
Art Unit: 1615

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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PATENT TRADEMARK OFFICE

Date: June 11, 2003

APPENDIX  
VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS:

The claims are amended as follows:

3. (Twice Amended) A process according to claim 1, characterized in that after the hydrolysis, but before being combined with the water-soluble ferric salt, the dextran is purified by one or more membrane separations having a cut-off value suitable for holding back dextran molecules above 2,700 Da, ~~possibly followed by further hydrolysis and one or more membrane separations having a cut-off value between 340 and 800 Da removing the smaller molecules.~~

6. (Twice Amended) A process according to claim 1, characterized in that the oxidation is performed by means of a hypochlorite, ~~preferably sodium hypochlorite~~ in basic aqueous solution.

7. (Twice Amended) A process according to claim 1, characterized in the following steps:

preparing an aqueous solution comprising the hydrogenated and oxidized dextran and at least one water-soluble ferric salt;  
adjusting the pH of said aqueous solution to a value above 10 by addition of a base;  
heating the mixture to a temperature above 100°C until it turns into a black or dark brown colloidal solution and is filterable through a 0.45 µm filter; and

purification and stabilization of the solution using filtration, heating and membrane separations and addition of one or more stabilizers, ~~and~~  
~~optionally drying the solution to obtain the desired iron-dextran compound as a stable powder.~~

8. (Amended) A process according to claim 7, characterized in that the stabilizsation comprises addition of at least one salt of an organic hydroxy acid, ~~preferably selected from citrates and gluconates.~~

10. (Twice Amended) Iron-dextran compound produced according to claim 1, characterized in that its apparent peak molecular weight (Mp) is 50.000-150.000 Da, ~~preferable 70.000-130.000, more preferable 80.000-120.000 Da~~ and its iron content is 15-45% b.w.

14. (Amended) A pharmaceutical composition according to claim 13, ~~characterized in that it comprises further comprising a salt of an organic hydroxy acid, preferably selected from citrates and gluconates as stabilizer.~~

15. (Amended) Use of an iron-dextran compound according to claim 10, for preparation of a parenterally administrable therapeutical composition for prophylaxis or treatment of iron-deficiency, ~~by parenteral administration comprising the following steps: providing the iron-dextran compound as an aqueous solution; and~~

sterilizing the composition.

16. (Amended) Use of a dextran preparation obtainable by a process according to claim 9, for the production of an iron-dextran compound in a process comprising the following steps:

mixing the dextran preparation as an aqueous solution with at least one water soluble ferric salt;  
heating the mixture to a temperature above 100 C until said mixture turns into colloidal solution that can be filtered through a 0.45 µm filter; and  
purification of the solution.

**Claims 17-33 are added as new claims.**